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Publications 2025

OPEN ACCESS
ONLINE ISSN: 2992-5479
PRINT ISSN: 2992-605X

NEWPORT INTERNATIONAL JOURNAL OF PUBLIC HEALTH AND PHARMACY (NIJPP)

Volume 6 Issue 2 Page 36-41, 2025

https://doi.org/10.59298/NIJPP/2025/623641

Green Chemistry in Pharmaceuticals: Reducing Environmental Impact

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ABSTRACT

The pharmaceutical industry is a major contributor to environmental pollution due to its reliance on hazardous chemicals, excessive waste production, and energy-intensive manufacturing processes. Green Chemistry (GC) offers a sustainable approach to pharmaceutical development by emphasizing waste reduction, energy efficiency, and the use of safer, renewable materials. This paper examines the principles of Green Chemistry and their application in the pharmaceutical sector, highlighting key strategies such as atom economy, catalysis, and solvent selection. Additionally, it reviews case studies of successful Green Chemistry implementation and discusses future challenges and opportunities for sustainable pharmaceutical production. The findings suggest that adopting Green Chemistry principles can lead to more cost-effective and environmentally friendly drug manufacturing while also complying with regulatory standards and meeting consumer demands for sustainable products.

Keywords: Green Chemistry, Sustainable Pharmaceuticals, Atom Economy, Catalysis, Solvent Selection, Waste Reduction.

INTRODUCTION

Green chemistry in the pharmaceutical industry has become increasingly important in the context of sustainability and persistence in today's society. Green chemistry strategies can affect the drug manufacturing process and delivery, as well as the discovery of new drugs. The pharmaceutical industry is one of the largest manufacturing sectors, and, as a result, an extensive amount of waste is generated from the extensive use of certain raw materials. Thus, the manufacturing of pharmaceutical compounds using current methods is associated with multiple disadvantages. Such methods usually require numerous chemical steps, with the addition of hazardous raw materials and the unnecessary production of large amounts of waste that could become dangerous, toxic, and flammable. The excess energy used to carry out chemical reactions, as well as the non-renewable resources utilized, are other downsides, capable of even further raising the cost of waste treatment. Additionally, the delivery and treatment of these drugs to the patient will also result in numerous disadvantages [1, 2]. While oral drug administration is considered a less aggressive external delivery path to the body, it also represents a huge drawback, with almost 99% of the drug not being absorbed through the organism for the intended actions, thus being eliminated by the patient. These compounds can reach the aquatic environment, even in their original form, which can lead to undesired effects. Traditional pharmaceutical manufacturing practices are associated with the need for larger investments, materials, and time, which may not be profitable. Green Chemistry emerges as an option for new methodologies that allow a decrease of the inconveniences associated with current drugs manufacturing, and their delivery and discovery. This science focuses on the design, synthesis, and development of drug products free from dangerous chemicals. It established twelve principles, specially designed to guide hazardous or toxic chemicals associated with the drug sector. This is a multidisciplinary philosophy that can be used by any type of company, regardless of size or scale of research, based mainly on waste minimization and prevention. The principles of GC or sustainable Chemistry (SC) have led to the possibility of developing new procedures that allow a

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PRINT ISSN: 2992-605X
continuing decrease of energy and chemical reactants, leading to the increase of atom economy and energy efficiency, in a cheap and fast manner [3, 4].

Principles of Green Chemistry

Green Chemistry represents an innovative and ambitious approach towards sustainable development and is used by chemists as guidance for developing new synthetic procedures. Green Chemistry provides suggestions for decreasing the environmental damage caused by chemical production. The principles of Green Chemistry were proposed in 1998 and have played a significant role in creating a global awareness of the need for more environmentally friendly industrial processes. The pharmaceutical industry is a major sector that has the potential to reduce environmental harm caused by synthetic chemical production if the postulates of Green Chemistry are followed. Intensive lobbying and intent from public stakeholders force pharmaceutical companies to adopt environmentally friendly syntheses, while consumers are increasingly aware of products that have been produced using processes with less environmental damage. Furthermore, numerous governmental regulations encourage pharmaceutical companies to diminish the environmental impact of their production [5, 6]. The environmental impact of chemical processes is mainly evaluated by the atom economy of the synthesis as well as the number of solvents and waste generated. The underlying factors of chemical methods indirectly affecting environmental damage include cultivating the biocidal activity of pharmaceuticals toward non-target species, limiting their extensive accumulation in the environment, and decreasing the use of non-renewable resources. The ideas of Green Chemistry are often embedded in the requirements of legal regulations, documents, or guidance [7, 8].

Atom Economy

Atom Economy is a central principle of Green Chemistry, as the efficiency of chemical reactions must be maximized. Maximizing the amount of useful product from a given amount of starting material is crucial, as whatever is not present in the reactants may end up as waste. As traditionally conducted, the vast majority of chemical processes in general and organic synthesis in particular are very wasteful of atoms. This is also recognized by the US EPA, which has defined the concept of "percent yield" and has estimated that, for example, in the fine chemicals sector of the chemical industry, only 4% of the mass is contained in the desired product. The concept of atom economy attempts to bring this issue to the attention of the chemical community by focusing on how effectively the atoms in a given reaction are utilized. In target-oriented organic synthesis, consideration of atom economy is a strategy that can lead to more sustainable ways of working. Therefore, the primary focus is on the negative attributes of atom inefficiency and its importance in the design of chemical processes. It is timely, however, given the ever-increasing industrial and regulatory interest in the application of green chemical principles, for the wider synthetic community to understand how these issues are interrelated. A new generation of rocket propellants has been designed using high atom economy processes, which, if they find wide application, have the potential to save the European rocket industry several billion ECU, and peanuts would once more be exported from Europe to America if some mild applications of a green chemical principle were adhered to during their growth and post-harvest handling. Biotech companies recently gained federal government approval to manufacture a chiral alcohol because a very high percent atom economy was achieved in the hydrolysis reaction. This equates, at the lower limit of production, to drug at $85 per dose, or $33,000 per kg. This approval raises the annual market for the alcohol by at least 200,000 kg, and in a typical batch production plant, the congressional revenue lost through the inability of the patenting company to trademark protect their intellectual property through secrecy is $216,000 per 18,000 kg batch [9, 10].

Catalysis

Catalysis is considered the 'oxygen' of Green Chemistry as it is this principle that can reduce the required energy input tremendously. Catalysts can be metals, often in trace amounts or even present in the metal grains of reactors or piping. Other catalysts are minerals in the form of zeolites or silicas, slightly modified or inorganic salts. Enzymes, as mechanics in biological systems, are the more confined and specific catalysts in nature. Nevertheless, all can decrease considerably the time of a chemical reaction, the energy input, or waste production, which has a considerable impact on its sustainability. There are now many reporting areas where the implementation of the catalytic process into the pharma industry is seen as the breath of survival, as with the first approach of L-DOPA synthesis biotransformation in the middle of the seventies [11, 12]. The Pharmaceutical industry is in the midst of a transformational change in its approach to the product development process. The global marketplace, combined with economic growth in emerging markets, is driving a need to manufacture products closer to the people who will consume them. A new industry landscape requires us to manufacture products faster, cheaper, and with much

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ONLINE ISSN: 2992-5479
PRINT ISSN: 2992-605X

greater flexibility while continuing to meet all social and regulatory requirements of standard industry practice. A new mindset to current processes and challenges will be required, and Green Chemistry tools and catalytic technologies may play a key role in enabling this new paradigm. Both Homogeneous and Heterogeneous Catalysis are established for a wide range of chemistries, but significantly, with the recent recognition of Green Catalysis as an Industrial Biotechnology, these technologies are capable of benefitting sustainability in Pharma batch manufacturing, leading to a durable and well-performing product synthesizing operation. The broadness and countermarch of catalytic technologies are considerable, in particular, challenges in the areas of catalyst recycling, specifically those of precious and rare-earth metals, and of CataCryst long-term stability limitations provide unique opportunities for innovative solutions and development of custom tools [13, 14].

Green Chemistry Techniques in Pharmaceutical Manufacturing

Among many branches of industry, the 'synthesis and manufacture of pharmaceutical compounds' is one of the most serious polluters. The results of recent studies indicate that "pharma" is responsible for significant soil and water pollution after cultivation, while significant amounts of solid pollution are generated at the final processing stage. That is the main reason that leads to searching for alternative technologies of good practice with the implementation of achievements in "Green Chemistry" in place of conventional processes harmful to the natural environment. Thus, as claimed in the literature, these processes can be considered as a set of principles enabling the realization of chemical syntheses in the range from the lowest to the highest level of environmental impact - expressed in terms of: the potential danger of used substances in the production and their by-products, the volume of liquid and solid waste or the method of their disposal, and also the energy consumption affecting the safety of the work performed. Although there are still many limitations resulting from some special requirements for the purity of products or problems associated with the regulation of pharmaceutical law, there is a conviction that the principles presented can, to some extent, be a model to build a future-oriented pharmaceutical industry [15, 16]. What can be considered as Green Chemistry in pharmaceutical manufacturing? Among many mechanisms of "Green Chemistry", some techniques can find practical use in the pharmaceutical industry, which can be usefully implemented, as long as there is awareness that these are the main objectives when designing or scaling synthesis processes. In a sense, the "Green Chemistry" movement is a subset of the broader effort to develop and maintain a more sustainable world. Some of these techniques, possible to implement mainly based on the rise of public awareness as a result of human activity hazards and the environment, have been universally cooperative over the past 15 years are as follows: selective hydrogenation in the presence of heterogeneous catalysts, the conversion of alcohols to narrow distribution esters, careful selection of solvents, the modification of the kinetics by the acidification of the medium, the conversion of gases and immiscible liquids in supercritical carbon dioxide and heterogenization of the reaction [10, 6].

Solvent Selection

The focus of these guidelines is on solvent selection, a critical aspect of pharmaceutical production, proposing practical advice to reduce its environmental impact. Over the last few years, the pharmaceutical industry has faced rising concerns over the environmental and health impacts of its activities. In particular, the role of solvents, which account for the bulk of the chemical substances employed during active pharmaceutical ingredients production, has been carefully scrutinized. Solvents such as acetonitrile, dichloromethane, and N-dimethylformamide, traditionally used in the pharmaceutical sector, are under regulatory pressure. The challenge of solvent evaluation and transition to greener alternatives is addressed, in agreement with Green Chemistry principles. Safer, less toxic, and preferably bio-based solvents of reduced consumption and waste generation represent a feasible green choice to improve the environmental profile of a process without affecting its industrial viability [17, 18]. It is important to establish universally acknowledged criteria for solvent evaluation since various accounts may be differently weighted according to different regulatory frameworks and industrial settings. A critical review of the environmental impact of pharmaceutical solvents is provided, discussing both published scientific literature and existing legislation. When making a careful selection, focus on an analysis of chemical toxins, while broader considerations, such as biodegradability, energy consumption, and methods for solvent assessment, are also discussed [19, 20]. The solvent category is often portrayed as detrimental to the API sector. Over the last years, a plethora of scientific and technical insights have been generated, confirming it as a well-established area of excellence within green chemical research and industrial practice. Green solvents may not only offer tangible benefits in terms of efficiency and cost, but the design of robust and highly clean processes can foster the discovery of novel reactions, reaction conditions, or new reaction pathways, offering a strategic advantage to nimble and forward-thinking

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ONLINE ISSN: 2992-5479
PRINT ISSN: 2992-605X
manufacturers. More opportunities are found in the future to further advance solvent selection guidelines, making them informed and comprehensive [21, 22].

Case Studies of Green Chemistry Implementation in Pharmaceutical Industry

Green Chemistry is especially needed in the pharmaceutical sector, bearing in mind the high impact on the environment and human health of the processes and of the emerging pollutants and the wastes generated. Research and implementation works are reported. 20 pharmaceutical companies: full members of the European Federation of Pharmaceutical Industries and Associations –EFPIA– were contacted, asking them if they were implementing green chemistry practices and how it was performed. The study was widened to the others associated members of EFPIA, 29 institutions and companies. It also reviewed the case of companies that have implemented green chemistry practices and the expected outcomes were fulfilled [6, 23]. At the end of the last century, the development of Green Chemistry motivated a different product and process design, avoiding or minimizing the synthesis and use of harmful products and wastes. The chemical industry was the first to profit by refining its processes, and some of the lessons learned can be applied to the pharmaceutical industry. The term green chemistry was defined by Anastas in the early 1990s, concerning the chemical products that are designed and manufactured in a way that minimizes their impact on patients and the environment. Since then, several principles have been defined, emphasizing the need for clean and efficient processes and the production of safe chemicals. The work of Bayer is an example of the incorporation of a green chemistry practice. In 1992, it became a member of the CEFIC –the European Chemical Industry Council– and a joint project with Bayer aimed to introduce the principles of green chemistry in the development of a new medicinal product. A committee was created formed by scientists and engineers that met once a month to analyze the route of synthesis of the active pharmaceutical product and its by-products [24, 25, 26].

Future Prospects and Challenges

There is an ardent need for ongoing research, reevaluation, and innovation of the present methods, prevention methodologies, and techniques for the successful reduction of the environmental burdens and other ecological risks associated with pharmaceuticals. For significant advancements in this field, a Green Chemistry approach, from the viewpoint of eco-friendly synthesis, newer environmentally benign comprehensive synthetic methodologies, greener durable materials, energy conservation, waste prevention, the reduction of hazardous materials, and policy issues are highlighted. The healthcare sector includes hospitals, clinics, pharmaceutical companies, and pharmaceutical production facilities and hence generates a very broad spectrum of waste, including pharmaceutical waste and packaging waste. Pharmaceuticals are harmful chemical compounds and pose very complicated environmental risks. The pharmaceutical industry is one of the most dynamic and innovative sectors, which is considered essential for modern society. The industry symbolizes substantial growth, but on the other hand, it indirectly generates complex environmental burdens and socioeconomic risks. Pharmaceutical pollution is not only emerging in developing nations; developed countries also face numerous hazards due to pharmaceuticals in the environment. The rising and irregular/unorthodox releases of the pharmaceuticals are anticipated as potential stimulants of pollution, and a Green Chemistry philosophy is necessary to adequately and efficiently address prescription and non-prescription drug pollution. There are many Green Chemistry-inspired strategies, including synthetic processes, alternative solvents, catalysis, and biocatalysis approaches, which are examined and employed to mitigate the unwanted toxicity and other impacts of drugs on ecosystems. Regulatory frameworks related to pharmaceutical pollution are relatively intensive in developed nations, whereas several developing nations still confront challenges because of their restricted economy and newly industrialized status. To combat pharmaceutical pollution, exacting new norms for harmful drug residues must be imposed, and compliance with current norms must be thoroughly controlled. Globally, the enhancement of public consciousness and enforcement activities are necessary to diminish pharmaceutical contamination. The environmental impacts from prescription drug leftovers, pharmaceuticals, or metabolites (often slightly altered medicine, stable absorbable compounds) have been enlarging quickly around the world in the last few years [27-31].

CONCLUSION

Green Chemistry presents a transformative approach for the pharmaceutical industry, promoting sustainability without compromising efficiency and profitability. By implementing strategies such as improved atom economy, catalytic reactions, and greener solvents, pharmaceutical companies can significantly reduce their environmental footprint. Despite challenges such as regulatory constraints and high initial costs, the long-term benefits—ranging from reduced waste disposal costs to compliance with stricter environmental laws—highlight the necessity of integrating Green Chemistry into pharmaceutical

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ONLINE ISSN: 2992-5479
PRINT ISSN: 2992-605X
manufacturing. Ongoing research, policy support, and industry commitment will be crucial in driving this transition toward a more sustainable pharmaceutical sector.

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CITE AS: Nyambura Achieng M. (2025). Green Chemistry in Pharmaceuticals: Reducing Environmental Impact. NEWPORT INTERNATIONAL JOURNAL OF PUBLIC HEALTH AND PHARMACY, 6(2):36-41. https://doi.org/10.59298/NIJPP/2025/623641